REMARKS/ARGUMENTS

Status of the Claims

Claims 61-65 were rejected. Claims 1-60 were previously canceled without prejudice or disclaimer. Applicants expressly reserve the right to file a continuation or divisional application or to take other such appropriate action to seek protection of the canceled subject matter.

Claim 64 has been amended to correct a minor typographical error. No new matter has been added by way of this claim amendment. New claims 66-69 have been added. Claims 61-69 are now pending in the present application. Reexamination and reconsideration of these claims are respectfully requested in view of the claim amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Rejection of the Claims Under 35 U.S.C. § 103 Should Be Withdrawn

Claims 61-65 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,525,030 (hereinafter "the '030 patent") and/or U.S. Patent No. 6,319,230 (hereinafter "the '230 patent") in view of U.S. Patent No. 6,503,231 (hereinafter "the '231 patent"), U.S. Patent No. 6,623,457 (hereinafter "the '457 patent"), and U.S. Patent No. 6,808,506 (hereinafter "the '506 patent") in further view of U.S. Patent No. 7,078,500. This rejection is respectfully traversed with respect to the pending claims.

Claims 61-63 are drawn to a method for inducing an immune response to a flaviviral antigen in a subject comprising delivering a vaccine expressing the flaviviral antigen to a subject's skin using a device that targets the intradermal compartment of the subject's skin. Claims 64 and 65 are directed to a kit for use in inducing an immune response to a flaviviral antigen in a subject, wherein the kit comprises a vaccine expressing the flaviviral antigen and a device that targets the intradermal compartment of the subject's skin. Accordingly, a feature of all of the pending claims is the presence of a vaccine expressing a flaviviral antigen. Flaviviruses are responsible for causing a number of conditions, including West Nile virus, dengue virus, Yellow Fever, and various forms of encephalitis.

The Examiner has cited a number of references to establish the obviousness of the instant claims. The '030 patent teaches direct gene transfer of genetic material into an external or internal target cell site. The '230 patent discloses a device and method for delivering and injecting fluid into heart tissue to increase fluid retention in that organ. The '231 patent is directed to microneedle devices for the transport of therapeutic and diagnostic materials across tissue barriers. The '457 patent describes a transdermal delivery device including a plurality of microneedles for injecting a substance (e.g., a pharmaceutical agent) into or below the stratum corneum of the skin. The '506 patent discloses an apparatus for delivering or withdrawing a fluid through at least one layer of skin. And finally, the '500 patent is drawn to recombinant nucleic acids that encode hepatitis C viral proteins, pharmaceutical compositions comprising these nucleic acids, and methods of immunizing individuals against the hepatitis C virus. One unifying feature of the extensive list of references cited by the Examiner, however, is that none of the patents mentions *any* flaviviral antigen or *any* vaccine expressing a flaviviral antigen, as recited in all of the present claims.

Establishing a *prima facie* case of obviousness requires assessment of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), which provides the framework for applying the statutory language of § 103. Under the "Graham Factors," the Examiner is required to:

1. Determine the scope and content of the prior art;
2. Ascertain the differences between the prior art and the claims at issue;
3. Resolve the level of ordinary skill in the pertinent art; and
4. Consider any relevant secondary considerations.

Furthermore, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) requires that the combination of references places the claimed subject matter in the public domain prior to Applicants' date of invention. See *In re Zenitz*, 333 F.2d 924, 142 USPQ 158 (C.C.P.A. 1964). Thus, establishing a *prima facie* case of obvious requires that the cited references can be combined such that each and every element of the claimed invention is taught, explicitly or implicitly, by the references and that a reasonable expectation of success exists in such a combination. In the instant case, the cited references do not disclose the recited claim element of a vaccine that expresses a flaviviral antigen, either explicitly or implicitly. Thus, the disclosures

of the cited references simply cannot be combined to arrive at the claimed methods or kits. As such, the claims are not obvious in view of the cited references, and the rejection of claims 61-65 under 35 U.S.C. § 103(a) should be withdrawn.

Furthermore, although the U.S. Supreme Court recently declined to permit a "rigid" application of the teaching-suggestion-motivation to combine (TSM) test to obviousness determinations, the Court did hold that the presence or absence of a teaching, suggestion, or motivation to combine the cited references provides a "helpful insight" regarding the obviousness of an invention. *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350, slip op. at 14 (U.S. Apr. 30, 2007). The Supreme Court went on to acknowledge the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in way the claimed invention does" in an obvious determination. *Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.*, No 06-1329, slip op. at 10 (U.S. June 28, 2007; citing *KSR Int'l Co. v. Teleflex, Inc.*). Although in the instant case the references simply cannot be combined to produce the claimed inventions, the Examiner has also merely provided broad conclusory statements and has failed to identify a sufficient reason that one of skill in the art would have been motivated to combine the plurality of reference and would have concluded that the claimed inventions are obvious in view of the combination.

Accordingly, in view of the above remarks, Applicants respectfully request that the obviousness rejection of claims 61-65 be withdrawn.

Newly submitted claims

New claims 66-69 have been added. Claims 66 and 67 are directed to methods for inducing an immune response to a flaviviral antigen in a subject comprising delivering a vaccine expressing the flaviviral antigen to a subject's skin using a device that targets the intradermal compartment of the subject's skin, wherein the vaccine is a chimeric Japanese Encephalitis vaccine (claim 66) such as JE SA14-14-2 (claim 67). Similarly, new claims 68 and 69 are drawn to kits for use in inducing an immune response to a flaviviral antigen in a subject, wherein the kits comprise a vaccine expressing the flaviviral antigen and a device that targets the intradermal

compartment of the subject's skin, wherein the vaccine is a chimeric Japanese Encephalitis vaccine (claim 68) such as JE SA14-14-2 (claim 69). Support for these newly submitted claims can be found in the specification as originally found in, for example, paragraphs [0058] through [0061]. As noted above, none of the cited references disclose *any* flaviviral vaccine and therefore also do not teach a Japanese Encephalitis vaccine. Accordingly, the references cited by the Examiner also do not render claims 66-69 obvious, and Applicants respectfully request that the present rejection not be applied to the newly submitted claims.

CONCLUSION

The Examiner is respectfully requested to withdraw the rejection of the claims and to not apply these rejections to newly submitted claims 66-69. In view of the above remarks and the claim amendments, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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